PILOT STUDY TO SHORTEN THE REVIEW CYCLE FOR NEW INVESTIGATOR R01 APPLICATIONS (NOT-OD-06–013)

Shortening the review cycle is a high priority for the National Institutes of Health (NIH) and the biomedical and behavioral research communities. There is also great interest in the career development of scientists, and NIH is committed to supporting new investigators in their efforts to obtain R01 research grant funding. Since new investigators, by definition, do not have R01 support, any delay in the ability to submit an amended application could have a negative impact on their careers. Cognizant of the pressure on new investigators to obtain NIH R01 funding, the Center for Scientific Review convened a trans-NIH working group to develop a process to shorten the referral and review cycle to permit a new investigator to submit an amended application for the next submission date. Although the number of new investigators who will be able to take advantage of this rapid turnaround process will be relatively small, the impact on the careers of these new investigators could be significant. The working group recommended an initial pilot, followed by an evaluation phase before consideration of modification and/or expansion. The results of this pilot will be analyzed and a determination made as to whether to expand this to all R01 applications submitted by new investigators. Further analysis will be done to determine if this should be expanded to all R01 applications and to consider if other grant mechanisms should be included. The pilot described in this notice is designed to shorten the time to the next review for some new investigators who are not successful in a R01 grant submission and are readily able to address the concerns raised and issues identified in the summary statement. Under carefully defined circumstances for this pilot, new investigators will be able to resubmit amended applications for the next review meeting rather than wait a cycle. This will shorten the time for the next consideration of the resubmission application by 4 months. Only R01 applications from investigators who meet the NIH definition of new investigators who are assigned to these study sections are included in this pilot. For the purposes of review and funding, applicants are considered new investigators if they have not previously served as the principal investigators on any Public Health Service–supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research career (K01, K08, and K12). Current or past recipients of Independent Scientist and other nonmentored career awards (K02, K04) are not considered new investigators.

Complete details are available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06–013.html>.

HIGH-DENSITY GENOTYPING OF DIABETES AND DIABETIC COMPLICATIONS SAMPLE COLLECTIONS (R01) (RFA-DK-06–005)

Release date: December 28, 2005
Letter of intent receipt date: March 14, 2006
Application receipt date: April 12, 2006

This request for applications (RFA) solicits applications for high-density genotyping of two large existing collections of genetic samples: Epidemiology of Diabetes and Its Complications (EDIC) and Genetics of Kidneys in Diabetes (GoKIND). Applicants should propose and justify a genotyping strategy, including the rationale for the sample size, sample selection, and genotyping method, along with a detailed analytic plan. However, no funding should be requested for whole-genome genotyping because the genotyping costs for whole-genome analyses will be borne separately by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Funds may be requested for limited genotyping or sequencing in candidate gene, fine mapping, or other restricted studies. This initiative is also intended to create a resource for future research, so genotyping data will be stored in an NIDDK repository and shared with the research community 1 year after it is generated. The participating institutes anticipate making five to seven awards in response to this RFA. The total amount to be awarded is up to $3.0 million for the first year and $2 million for each of 2 additional years, for a total of 3 years. This RFA will use the R01 mechanism. Funding decisions will also take into account the uniqueness (nonredundancy) of the application.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-06–005.html>.

REPLICATION OF HIGHLY PATHOGENIC AVIAN INFLUENZA VIRUSES IN SWINE (RFA-CI-06–005)

National Center for Infectious Diseases (NCID)
Centers for Disease Control and Prevention (CDC)
Release date: December 29, 2005
Letter of intent receipt date: January 23, 2006
Application receipt date: February 22, 2006

The main goal of this study is to establish the susceptibility of swine to infection with Asian strains of HPAI H5N1

and their potential role in the emergence of pandemic strains. The experimental design should take into account the need to make the study relevant for the conditions expected in the field, for example, use of intranasal or oral and pharyngeal routes of virus inoculation, viral challenge doses representative of the range of natural exposure conditions, and sampling methods that allow accurate assessment of the virus and its replication in specimens collected. This funding opportunity will use the U01 award mechanism and uses the just-in-time budget concepts. It also uses the nonmodular budget format described in the PHS 398 application instructions. A detailed categorical budget for the initial budget period and the entire proposed period of support is to be submitted with the application. The CDC U01 is a cooperative agreement award mechanism. In the cooperative agreement mechanism, the principal investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with CDC staff being substantially involved as a partner with the principal investigator. This request for applications is a one-time solicitation. The NCID intends to commit approximately $800,000, including direct and indirect costs in FY 2006, to fund approximately two new cooperative agreement awards at $400,000 each, including direct and indirect costs for the first 12-month budget period. The ceiling of award range is $400,000, including direct and indirect costs. An applicant may request a project period for up to 2 years. The anticipated start date for the new award is July 2006. All estimated funding amounts are subject to the availability of funds.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CI-06–005.html>.

STUDIES TO UNDERSTAND TRANSMISSIBILITY OF INFLUENZA VIRUSES IN MAMMALIAN SPECIES (RFA-CI-06–004)

National Center for Infectious Diseases
Centers for Disease Control and Prevention
Release date: December 29, 2005
Letter of intent receipt date: January 23, 2006
Application receipt date: February 22, 2006

The purpose of this request for applications (RFA) is to support research to better understand the transmissibility of influenza viruses, particularly avian viruses to mammalian species. It is anticipated that two awards may be funded at a total cost of $300,000 each, including direct and indirect costs, with a ceiling award range of $300,000, including direct and indirect costs, with an anticipated start date of July 2006. This RFA is a one-time solicitation and will use the cooperative agreement (U01) mechanism. Eligible organizations include for-profit or nonprofit organizations, public or private institutions (eg, universities, colleges, hospitals), units of state and local governments, eligible agencies of the federal government, domestic institutions, North American Free Trade Agreement Countries, and faith- or community-based organizations.

Application materials are available at <http://www.cdc.gov/od/pgo/forminfo.htm>. Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CI-06–004.html>.

RFP ANNOUNCEMENT: HIGH-PRIORITY INFLUENZA RESEARCH AREAS (NOT-AI-06–011)

National Institute of Allergy and Infectious Diseases (NIAID)

Research aimed at developing tools to control epidemic influenza and the increasing threat of pandemic influenza is one of NIAID's highest priorities. Influenza is both a major public health threat and a NIAID Biodefense Category C priority pathogen (<http://www2.niaid.nih.gov/Biodefense/bandc_priority.htm>). NIAID is issuing this notice to the National Institutes of Health guide to highlight its interest in receiving grant applications focused on influenza research. Areas of high priority include but are not limited to the following:

- Development of improved drugs against influenza, including structure and function studies of influenza virus proteins, with the goal of identifying new therapeutic targets
- Development of novel influenza vaccines and vaccination strategies; novel approaches might include developing and evaluating new vaccine formulations, adjuvants, immune response stimulators, protective T-cell and antibody epitopes, new routes of delivery, common epitope vaccines, and alternatives to egg-based vaccine production technologies
- Development of sensitive, specific, and rapid clinical diagnostic tests for influenza
- Evaluation of the immune response to infection and/or vaccination, including cell-mediated and innate immunity
- Determination of the molecular basis of the virulence of influenza viruses in humans and animals
- Evaluation of the molecular and/or environmental factors that influence the transmission of influenza viruses, including drug-resistant strains
- Studies on the evolution and emergence of influenza viruses, including the identification of factors that affect influenza host range and virulence
- Virologic and serologic surveillance studies of the distribution of influenza viruses with pandemic potential in animal populations and in humans at the human-animal interface

Applications on influenza may be submitted under any of the following appropriate NIAID programs that are currently available.

Grants

Biodefense and Emerging Infectious Disease Research Opportunities (PA-04–119)
SBIR Advanced Technology – NIAID (SBIR-AT-NIAID) (PA-04–127)
Small Business Innovation Research Program Parent Announcement (PA-06–006)
Small Business Technology Transfer Program Parent Announcement (PA-06–007)
NIH Small Research Grant Program (R03) (PA-03–108)

Contracts

NIAID Centers of Excellence for Influenza Research and Surveillance (NIH-NIAID-DMID-BAA-07–20)

Additional information can be obtained by contacting the program contact listed in the individual announcements above. Additional details about this Request for Proposals can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-AI-06–011.html>.

RESEARCH ON PATHWAYS LINKING ENVIRONMENTS, BEHAVIORS, AND HIV/AIDS (R01) (PAR-06–114)

National Institute of Child Health and Human Development
National Institute on Aging
National Institute on Drug Abuse
National Institute of Mental Health
Release date: December 27, 2005
Letter of intent receipt date: not applicable
AIDS application submission dates: September 1, 2006, 2007, and 2008

This program announcement calls for research studies on the relationships among social environments, individual behaviors, and the incidence and prevalence of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) in populations. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received. This Program Announcement uses the R01 mechanism.

Complete details are available at <http://grants.nih.gov/grants/guide/pa-files/PAR-06–114.html>.

PHASED INNOVATION AWARDS (R21/R33) IN AIDS VACCINE RESEARCH (PA-06–109)

National Institute of Allergy and Infectious Diseases
Release date: December 23, 2005
Application submission date: May 1, 2006

Applications are being sought for Phased Innovation Awards (PIA) in acquired immune deficiency syndrome (AIDS) vaccine research, a continuation and modification of the previous program announcement (PA), Innovation Grant Program for AIDS Vaccine Research. This program will support prophylactic vaccine research projects that are innovative and novel, that may be high risk or high impact, and that exhibit the potential to advance AIDS prophylactic vaccine design or evaluation. All areas of investigation contributing to the development of an efficacious human immunodeficiency virus (HIV)/AIDS vaccine are welcome. Clinical trials will not be supported under this initiative. Awards will support milestone-driven exploratory/feasibility "proof of concept" studies (2-year R21 phase), with possible rapid transition to expanded development (2- to 3-year R33 phase). Initially funded R21 studies will be tested over 2 years via milestone completion, and eligible R21s will be further assessed for the R33 award.

Funding will be based on scientific and technical merit, program priorities, and the availability of funds. The R21 award will be limited to $275,000 directs over the 2-year award period, and the R33 award will be limited to $300,000 in direct costs per annum. The National Institutes of Health anticipates that a maximum of 50% of the funded R21 phase awards will progress to the R33 award. The R21/R33 PIA application must be submitted as a single application, and applicants should note specific instructions for each phase. Applicants may submit multiple applications. The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format.

Applicants must use the currently approved version of the PHS 398. For further assistance, contact GrantsInfo, telephone 301–435–0714, e-mail: GrantsInfo@nih.gov.

Complete details are available at <http://grants.nih.gov/grants/guide/pa-files/PA-06–109.html>.

RESEARCH ON THE COGNITIVE SEQUELAE OF PARKINSON'S DISEASE (R01) (PA-06–105)

National Institute of Neurological Disorders and Stroke (NINDS)
National Institute on Aging (NIA)
National Institute of Nursing Research (NINR)
Release date: December 22, 2005

Under this program announcement (PA), NINDS, NIA, and NINR invite research grant applications that address the underlying neurobiologic mechanisms associated with cognitive impairment in Parkinson's disease (PD), that address the development of clinical interventions and therapeutics for cognitive impairment in PD, or that promote improved clinical diagnosis or treatment of cognitive impairment in PD. A goal of this PA is to begin a process by which basic and clinical scientists from various

disciplines can overcome barriers to cross-disciplinary and biobehavioral research and examine all aspects of cognition in the context of the diagnosis and treatment of PD. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received. The number of awards made under this solicitation will depend on the overall scientific merit of the applications and the availability of funds. This PA uses the R01 mechanism. Eligible principal investigators include any individual with the skills, knowledge, and resources necessary to carry out the proposed research. Applicants may submit more than one application provided that they are scientifically distinct. This PA is one of three coordinated programs being released by NINDS to promote research on the nonmotor aspects of PD, including Research on the Cognitive Sequelae of Parkinson's Disease (R03) (PA-06–106) and Research on the Cognitive Sequelae of Parkinson's Disease (R21) (PA-06–107).

Complete details are available at <http://grants.nih.gov/grants/guide/pa-files/PA-06–105.html>.

Announcements have been made for R03 and R21 grants as well (in respective order): <http://grants.nih.gov/grants/guide/pa-files/PA-06–106.html>; <http://grants.nih.gov/grants/guide/pa-files/PA-06–107.html>.

GENOME SEQUENCING CENTERS (U54) (RFA-HG-06–001)

National Human Genome Research Institute (NHGRI)
Release date: December 22, 2005
Letter of intent receipt date: January 11, 2006
Application receipt date: April 11, 2006

This solicitation seeks renewal of NHGRI's large-scale sequencing program. This program has successfully completed the human genome sequence, the genomic sequence of several major biomedical model systems, and is currently emphasizing comparative genomic sequencing to provide a foundation for identifying and understanding conserved functional sequences in the human sequence. More recently, the program has begun to turn its attention to medical sequencing, including the identification of genomic changes implicated in disease. NHGRI intends to renew its large-scale sequencing program, continuing its record of increasing production and decreasing costs over time and continuing its emphasis on contributing to understanding the underlying role that deoxyribonucleic acid (DNA)-based changes contribute to biologic systems. During the next 4 years, NHGRI anticipates that the type and number of important large-scale sequencing products will expand, requiring new flexibility from the components of the program. Up to $420 million in total costs will be awarded over 4 years at a level of not more than $130 million per year, and it is anticipated that three to five awards will be made. The awards will be made using the National Institutes of Health (NIH) Specialized Center-Cooperative Agreement (U54) mechanism. Eligible principal investigators with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH programs. Applicants may not submit multiple applications.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-06–001.html>.

BIOMARKERS OF AUTOIMMUNITY IN TYPE 1 DIABETES (R21) (RFA-DK-06–002)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Allergy and Infectious Diseases
National Institute of Child Health and Human Development
Release date: December 28, 2005
Letter of intent receipt date: March 14, 2006
Application receipt date: April 12, 2006

Two areas of great need in type 1 diabetes are the prediction and early detection of autoimmune destruction of pancreatic beta cells and biomarkers for ongoing autoimmune disease, which could be used to monitor responses in clinical trials. This request for applications (RFA) is intended to facilitate progress in this area by soliciting new applications focused on the detection of the human autoimmune response in type 1 diabetes. To be considered responsive, proposed approaches must have the potential to lead to the development of a test useful in a clinical setting. This RFA will use the R21 mechanism. The participating institutions plan to contribute $2 million to fund five to seven new awards. Applicants can request a project period of up to 2 years. Applicants may submit more than one application provided that they are scientifically distinct.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-06–002.html>.

TOWARD IMAGING THE PANCREATIC BETA CELL IN PEOPLE (R01) (RFA-DK-06–003)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Aging
National Institute of Allergy and Infectious Diseases
National Institute of Biomedical Imaging and Engineering
Release date: December 13, 2005
Letter of intent receipt date: March 14, 2006
Application receipt date: April 12, 2006

This request for applications (RFA) is intended to facilitate progress in imaging the pancreatic beta cell by soliciting

new and competing continuation applications focused on in vivo detection of beta cell mass, function, inflammation, or transplanted islet engraftment, especially using imaging technologies. This RFA is also intended to support the development of novel imaging technologies that will provide new opportunities for evaluating and quantifying beta cell mass and function. To be considered responsive, proposed approaches must have the potential to lead to the development of a clinically useful examination. It is not, however, required that applications propose studies using human subjects. This RFA will use the R01 mechanism. The participating institutions plan to contribute $2,250,000 to fund three to six new awards. Applicants can request a project period of up to 3 years. Applicants may submit more than one application provided that they are scientifically distinct.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-06–003.html>.

INNOVATIVE TECHNOLOGIES FOR MOLECULAR ANALYSIS OF CANCER (R21, R33) (RFA-CA-07–001)

National Cancer Institute (NCI)
Release date: December 8, 2005
Letter of intent receipt dates: January 23, 2006; April 26, 2006
Application receipt dates: February 22, 2006; May 26, 2006

NCI invites applications for research projects proposing the development of highly innovative cancer-relevant molecular technologies. Technology encompasses methods and tools that enable research, including but not limited to instrumentation, techniques, and devices. Molecular technologies are distinct from resources such as databases, individual reagents, therapeutic agents, and tissue repositories and do not include the development of whole-body imaging technologies. Repositories, agent development, whole-body imaging technologies, and software development are supported through other initiatives. This request for applications (RFA) will use the NIH R21 Exploratory/Developmental and the R33 Exploratory/Developmental Phase 2 award mechanisms. (Please note that this funding opportunity announcement does not solicit and will not accept combined R21/R33 phased innovation applications.) The R33 mechanism provides a second phase for the support of innovative exploratory and developmental research that may or may not have been initiated under the R21 mechanism. NCI intends to commit approximately $3,000,000 in FY 2007 to fund 10 to 15 new and/or competing continuation grants in response to this RFA. An applicant for an R21 grant may request a project period of up to 2 years and a budget for total direct costs of up to $275,000, in keeping with standard R21 mechanism guidelines. An applicant for an R33 grant may request a project period of up to 3 years and a budget appropriate for the science proposed. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award, especially in the case of R33 awards, will also vary. An applicant may submit an unlimited number of unique applications in response to this announcement. Applicants may submit more than one application provided that they are scientifically distinct.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07–001.html>.

APPLICATION OF EMERGING TECHNOLOGIES FOR CANCER RESEARCH (R21, R21/R33, R33) (RFA-CA-07–002)

National Cancer Institute (NCI)
Release date: December 8, 2005
Letter of intent receipt dates: January 23, 2006; April 26, 2006
Application receipt dates: February 22, 2006; May 26, 2006

NCI invites applications for research projects to evaluate the usefulness of emerging molecular technologies that are ready for initial application to clinical or biologic questions in cancer research. Technology encompasses methods and tools that enable research, including but not limited to instrumentation, techniques, and devices. Molecular technologies are distinct from resources such as databases, individual reagents, therapeutic agents, and tissue repositories and do not include the development of whole-body imaging technologies. Repositories, agent development, whole-body imaging technologies, and software development are supported through other initiatives. This funding opportunity will use the National Institutes of Health R21 Exploratory/Developmental Award, R21/R33 Phased Innovation Award, and R33 Exploratory/Developmental Phase 2 Award mechanisms. NCI intends to commit approximately $3,000,000 in FY 2006 to fund six to eight new and/or competing continuation grants in response to this funding opportunity. An applicant for an R21 grant may request a project period of up to 2 years and a budget for total direct costs of up to $275,000, in keeping with standard R21 mechanism guidelines. An applicant for an R33 grant may request a project period of up to 3 years and a budget appropriate for the science proposed. A combined R21/R33 applicant may request a project period of up to 4 years, of which the R21 portion may be no more than 2 years. An applicant may submit an unlimited number of unique applications in response to this announcement. Applicants may submit more than one application provided that they are scientifically distinct.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07–002.html>.

ADVANCED PROTEOMIC PLATFORMS AND COMPUTATIONAL SCIENCES FOR THE NCI CLINICAL PROTEOMIC TECHNOLOGIES INITIATIVE (R01, R21, R21/R33) (RFA-CA-07–005)

National Cancer Institute (NCI)
Release date: December 8, 2005
Letter of intent receipt date: March 11, 2006
Application receipt date: April 11, 2006

NCI invites applications for research project grants to support highly innovative research in the quantitative analysis of proteins and peptides of interest in clinical cancer studies. This funding opportunity is a component of NCI's Clinical Proteomic Technologies Initiative for Cancer (<http://proteomics.cancer.gov>). The program aims to improve the technological capability to reliably identify, quantify, and compare measurements and analyses of proteins and peptides in complex biologic mixtures. NCI intends to commit approximately $10 million in FY 2006 to fund approximately 10 new grants in response to this funding opportunity. This funding opportunity involves the use of the NIH R01, R21, and combined R21/R33 grant mechanisms. Applicants applying for advanced proteomic technology platform development will use the R21 Exploratory/Developmental Award or the R21/R33 Phased Innovation Award. For the R21 Exploratory/Developmental Award, an applicant may request a project period of up to 2 years and a budget for direct costs of up to $275,000, in keeping with standard R21 mechanism guidelines. Applicants applying for the R21/R33 Phased Innovation Award may request a project period of up to 4 years, of which the R21 portion may be no more than 2 years. Projects in technology development using the R21 or combined R21/R33 mechanism must include quantitative performance "milestones" that are directly related to the specific aims (see Section IV.2). Applications for the R33 award alone will not be accepted. Applicants applying for research projects grants that support data analysis methods and computational sciences will use the R01 award mechanism.

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07–005.html>.

CORRECTIONS

Please note that the text on page 34, column 2, line 1, in the article "Current Science of Regenerative Medicine with Stem Cells" (2006;54(1):33–37) contained an outdated reference. The sentences should read as follows:

"South Korean researchers recently claimed creation of scores of cloned human embryos from patients and production of 11 ES cell lines.[24] These claims have now been proven fraudulent and the published paper withdrawn. It is still uncertain whether the cells would actually be accepted by the patient's immune system, and prominent ES cell researchers have questioned the efficiency of using therapeutic cloning for clinical use.[25,26]"

In addition, the in-text reference citations on pages 34 and 35 in the section titled "Adult Stem Cells" of the article "Current Science of Regenerative Medicine with Stem Cells" (2006;54(1):33–37) were inaccurate. In column 2, paragraph 1, line 8, the in-text citation of Reference 31 should be to Reference 32; on line 12, the in-text citation of Reference 32 should be to Reference 33; and so on to the end of the article. The "References" list is correct.

Please also note that the title of Abstract 323, presented at the 2006 Western Regional Meeting February 1–4, 2006, in Carmel, CA, (2006;54(Suppl 1):S135) was not listed correctly. The correct title on that page and in the Western Abstracts Program (2006;54(Suppl 1):S49) should be "In Vivo Lipoprotein Lipase-Mediated Triglyceride Metabolism in the Human Heart."